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| EXAMINER |
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WHALEY, PABLO S

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| ART UNIT | PAPER NUMBER |
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1631

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03/07/2012

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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|------------------------------|--------------------------------------|--|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/597,767 | <b>Applicant(s)</b><br>SCHAFFER ET AL. |  |
|                              | <b>Examiner</b><br>PABLO WHALEY      | <b>Art Unit</b><br>1631                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 September 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on \_\_\_\_; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 5) ☒ Claim(s) 1,3-24 and 26 is/are pending in the application.
- 5a) Of the above claim(s) 3, 4, 7, 8, 22, and 23 is/are withdrawn from consideration.
- 6) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 7) ☒ Claim(s) 1,5,6,9-21,24 and 26 is/are rejected.
- 8) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 9) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____.                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____.  | 6) <input type="checkbox"/> Other: ____.                          |

## **DETAILED ACTION**

### ***Prosecution Reopened***

1. In view of the appeal brief filed on 09/19/2011 and an updated search of the prior art, PROSECUTION IS HEREBY REOPENED. Newly applied rejections are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

/Marjorie Moran/

Supervisory Patent Examiner, Art Unit 1631

### ***Telephone Election***

During a telephone conversation with Thomas Lundin on 02/17/2012 to clarify election vs. lack of unity practice, the election with traverse of Group I, claims 1-12, 15-17, 10, and 21-26 was confirmed. However, the examiner had forgotten that non-elected claims 13, 14, 18, and 20 of

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Group II had already been rejoined with elected claims in the Final Office action. Therefore the election and traversal regarding the restriction is moot. The examiner apologizes for any confusion.

The species election is still considered proper and is maintained. Applicant is assured that upon a finding of allowable of generic claims, any nonelected species claims which depend from the allowable generic claims will be rejoined and fully examined.

### ***Applicant's Response***

Applicant's amendments and remarks, filed 09/19/2011, are acknowledged.

The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

### ***Status of Claims***

Claims 2 and 25 are cancelled.

Claims 1, 3-24, and 26 are pending.

Claims 3, 4, 7, 8, 22, and 23 are withdrawn.

Claims 1, 5, 6, 9-21, 24, and 26 are under examination.

### ***Withdrawn Rejections***

The rejections of claims 1, 2, 5, 6, 9-21, 24, and 26 under 35 U.S.C. 103(a) as being unpatentable over Ooi et al. in view of Chtioui and Liu et al. are withdrawn after further consideration. Accordingly, applicant's arguments are moot in view of the new grounds of rejections, applied below.

***Claim Rejections - 35 USC § 112, 2<sup>nd</sup> Paragraph – Newly Applied***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The essential inquiry pertaining to this requirement is whether the claims set out and circumscribe a particular subject matter with a reasonable degree of clarity and particularity. Definiteness of claim language must be analyzed, not in a vacuum, but in light of: (A) The content of the particular application disclosure; (B) The teachings of the prior art; and (C) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made.

Claims 1, 5, 6, 9-21, 24, and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims that depend directly or indirectly from claim(s) 1, 15, and 21 are also rejected due to said dependency.

Claims 1, 15, 19, and 21 are directed to methods for determining a classifier that result in “*selecting a classifier that uses the sub-set of associated measurements specified by the...genes of a chromosome identified by the genetic evolving.*” This phrase is confusing for the following reasons.

With regards to “*selecting a classifier that uses the sub-set of associated measurements specified by the...genes of a chromosome*” it is unclear what positive process limitation is intended. If applicant intended for this step to result in selecting a classifier, this is not clear because no limitations are set forth to indicate how this selection is being made (other than an apparent intended use recitation). Furthermore, the previous steps in the claims result in producing an evolved set of genes which do not appear to have any relationship to classifiers. Therefore, it is unclear in what way the claims actually result in “selecting a classifier”, as

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claimed. The intended use of the "sub-set of associated measurements" has no limiting effect on the claimed method. As it is unclear what positive process limitations are being employed for selecting a classifier, the claims are indefinite.

With regards to the phrase "identified by the genetic evolving", it is unclear what limiting effect is intended by this phrase because none of the previous steps has "identified" anything. As it is unclear what has been (or is intended to be) identified, the claims are indefinite.

Claims 5 and 6 depend from cancelled parent claim 2 and therefore are rejected for being incomplete [See MPEP 608.01(n), Section V]. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claims 11 and 12 recite 'wherein' clauses that include the phrase "*for classifying a group of measured subjects into two or more classifications*". It is unclear whether this is intended to be an intended use limitation (of the fitness criterion), an active method step for performing classification, or otherwise. Therefore, as it is unclear what limiting effect is intended, the claim is indefinite.

Claim 12 recites "*splitting a set of measured subjects into a training group and a random test group*". It is unclear what the "measured subjects" is referring to. There is no previously mention of any steps for measuring anything, nor is there any prior mention of subjects or measured subjects. Accordingly, the claim is indefinite.

### ***Claim Rejections - 35 USC § 103- Newly Applied***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 5, 6, 9-12, 15-17, 19, 21, 24, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whitley (A Genetic Algorithm Tutorial, 1993, pp.1-38; IDS filed 08/07/2006).

For purposes of examination, claims 1, 15, 19, and 21 are directed to methods for generating chromosomal populations using a genetic algorithm. The methods, as best understood, require (i) producing a first generation chromosome population comprising chromosomes, wherein each chromosome has a selected number of ordered genes specifying a

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sub-set of associated measurements, and an expressed sub-set-size gene containing an ordinal position value separating expressed and unexpressed genes, which are interpreted as binary digits (since the claims do not recite any positive limitations for obtaining measurements); (ii) genetically evolving the genes of the chromosomes using a fitness criterion evaluated without reference to unexpressed genes to produce successive generation chromosome populations, wherein the genetic evolving is performed by computer and includes mating pairs of parent chromosomes to generate offspring, and (iii) selecting a classifier, which is interpreted as an optimal solution, based on a sub-set of associated measurements specified by the expressed genes.

Whitley teaches methods for producing chromosome populations using genetic algorithms. Regarding claim(s) 1, 15, 19, 20, and 21, Whitley shows producing an intermediate generation population comprising a plurality of ordered (i.e. indexed) strings, each of which represents a genotype or a chromosome (pp.4-5, Section 2 and Figure 1). Each string (i.e. chromosome) is represented as an ordered binary sequence of binary digits (page 6), wherein each bit is associated with a binary value and a position (pages 6 and 7, and Table 1). Therefore, Whitley inherently teaches chromosomes having an ordered sub-set of genes that contain index values associated with binary digits (i.e. measurements), as in step (i). With regards to "expressed sub-set-size genes", Whitley is silent to this term. However, Whitley suggests this limitation by teaching chromosomes represented using sequences of binary digits, which are interpreted as sub-set-size genes, as in step (i), since they are inherently associated with positional values separating expressed and unexpressed genes, as discussed above. In this case, the 0's and 1's represent unexpressed and expressed genes, respectively.

Whitley teaches computationally genetically evolving the intermediate population to generate an offspring population of chromosomes according to a fitness criterion (Figure 1 and pages 5-6, Table 1), as in step (ii). Whitley does not specifically teach a computer for performing the above process. However, Whitley suggests this limitation by teaching executable computational algorithms that require a computer in order to perform the processing (Section 7).

Whitley does not specifically teach genetically evolving the genes of the chromosomes using a fitness criterion evaluated without reference to unexpressed genes to produce successive generation chromosome populations. However, Whitley suggests this limitation by providing reduction techniques for performing mating that remove bits that strings have in common (page 19, Section 4.3). The removed bits can be arbitrarily selected as 0's or 1's. Therefore Whitley makes obvious the step genetically evolving the genes of the chromosomes without reference to unexpressed genes (i.e. 0's).

Whitley does not specifically teach selecting a classifier that uses the sub-set of associated measurements specified by the expressed genes. However, this limitation is being interpreted as an optimal solution. Therefore, Whitley suggests this limitation because each string represents a possible solution to a parameter optimization problem (page 6) and provides methods for selecting an optimal solution (Section 8, page 29), as in step (iii).

Regarding claim(s) 5, 6, and 21, Whitley teaches genetically evolving genes using a selection criteria that fills genes of the offspring with gene values common to both parent chromosomes (page 6, ¶3, ¶4). In one case, the genetic algorithm fills the first three bits of each string explicitly while the remainder of the bit strings are unspecified (page 9, last ¶, and Table 1), which makes obvious steps (i) and (ii) of claim 5. Whitley also shows that new strings are

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biased toward regions that have previously contained strings that were above average (page 11, last two ¶s). With regards to occasionally varying the ordering of the common gene values, Whitley teaches recombination of strings based on crossover and mutation (Figure 5), which results in occasional variation of the order of common gene values.

Regarding claim(s) 9 and 10, Whitley teaches that parents survive until they are replaced by better solutions obtained through the evolutionary process and fitness (page 5, last two ¶s, and Section 8). Whitley also teaches methods for provided offspring with a reduced number of expressed genes, as set forth above. Whitley teaches various methods for selecting offspring that are the most fit and least fit (Figure 3, Tables 1 and 2, Section 8.2).

Regarding claim(s) 11, 12, and 26, Whitley teaches a fitness criterion that indicates the fitness of the sub-set association measurements (Table 1). With regards to ‘wherein’ clause limitations directed to classifying a group of measured subjects, these limitations are interpreted as intended use limitation and therefore have no limiting effect on the claimed methods. With regards to the limitation for introducing simulated noise into values of measurements, Whitley suggests this limitation by introducing “\*” symbols into strings which represent “don’t care” symbols, which are interpreted as noise as the specification does not provide a limiting definition for noise that would suggest otherwise. With regards to randomly splitting a set of measured subjects, Whitley shows that the initial population of chromosomes comprising binary bits (i.e. measured subjects) is generated randomly (Section 2), and teaches splitting bits during crossover (page 13), which suggests splitting of subjects. Whitley also teaches mating for generating offspring (pages 5-6 and 34, last two ¶s).

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Regarding claim(s) 15 and 19, Whitley makes obvious the steps for filling genes of the offspring, as set forth above, and additionally teaches replacing parents based on fitness criteria (page 5 and page 29 , Evolution Strategies), which reads on updating the chromosome population as claimed.

Regarding claim(s) 16, Whitley does not specifically teach a mutation rate for the selective mutating of the gene values that are unique to one or the other of the parent chromosomes that is greater than 5%. However, this limitation is considered to be an arbitrary design parameter and Applicant has not disclosed that this particular limitation provides an unexpected result or in any way further limits the function of the claimed process. Therefore, at the time the invention was made, one of ordinary skill in the art would have expected that the method of Whitley could have been modified to use mutation rates, as claimed, because Whitley teaches a mutation operator that is applied to each bit (gene) in the population that is associated with a probability of less than 1% (page 6, ¶2). Therefore, it would have been prima facie obvious to modify the method, as claimed, because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Whitley.

Regarding claim(s) 17, Whitley teaches expressing sub-sets of genes of each chromosome with an associated fitness value (Table 1). For these reasons, the prior art of Whitley teaches and/or makes obvious the claimed limitations.

Claims 13, 14, 18, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whitley (A Genetic Algorithm Tutorial, 1993, pp.1-38; IDS filed 08/07/2006), as applied to

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claims 1, 5, 6, 9-12, 15-17, 19, 21, 24, and 26, above, and further in view of Ooi et al. (Bioinformatics, 2003, Vol. 19, No. 1, p.37-44).

Whitley makes obvious a method for generating chromosomal populations using a genetic algorithm, as set forth above.

Whitley does not teach medical diagnostic tests for determining whether a subject has a pathology by classifying measurements of the medical subject using classifiers, as in claims 13, 14, 18, and 20.

Ooi teaches the use of genetic algorithm for classifying gene expression data obtained from tumor samples (page 39-40, MLHD Classifier section). The method includes the use of fitness criteria for performing multi-class predictions. Ooi teaches Cy5/Cy3 ratios, which correlate to concentrations of fluorescent markers. Ooi teaches a data set comprising 14 classes of tumors is classified using the GA; see page 43, Col. 1, which shows using a medical diagnostic classifier for classification into positive and negative groups, since the results are associated with an error rate (i.e. 18% error), which implies 82% positive classification). Data sets are obtained from microarrays (p.38, col. 2).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to have performed medical diagnostic tests for determining whether a subject has a pathology using genetic algorithm classifiers of Whitley, since methods for performing medical diagnosis by applying genetic algorithms to chromosomal data sets with predictable results were known in the art, as taught by Ooi, and since computational methods for programming a computer to process chromosomal data sets using genetic algorithm techniques

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would have been known in the art, in view of Whitley and Ooi. The rationale would have been combining known elements according to known methods to yield predictable results.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pablo Whaley whose telephone number is (571)272-4425. The examiner can normally be reached between 11am-7pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached at 571-272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Pablo S. Whaley/

Examiner, Art Unit 1631